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19 MAY 2005

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITYTo:
JANE MASSEY LICATA
LICATA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053Docket System
Status Report
Docket Book
8/27/04
W0

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing
(day/month/year)

27 JUL 2004

Applicant's or agent's file reference

DC-0243

REPLY DUE

within 1 months/days from
the above date of mailing

International application No.

PCT/US03/34771

International filing date (day/month/year)

31 October 2003 (31.10.2003)

Priority date (day/month/year)

13 November 2002 (13.11.2002)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/00, 60 and US Cl.: 435/4, 11, 40.5

Applicant

TRUSTEES OF DARTMOUTH COLLEGE

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I ☒ Basis of the opinionII ☐ PriorityIII ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV ☐ Lack of unity of inventionV ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI ☐ Certain documents citedVII ☐ Certain defects in the international applicationVIII ☐ Certain observations on the international application3. The applicant is hereby **invited to reply** to this opinion.**When?** See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.**Also** For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 13 March 2005 (13.03.2005).

Name and mailing address of the IPEA/US

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Ruth A. Davis

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Form PCT/IPEA/408 (cover sheet)(July 1998)

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-22, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the claims:
 pages 23 and 24, as originally filed
 pages NONE, as amended (together with any statement) under Article 19
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☒ the drawings:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages NONE, as originally filed
 pages NONE, filed with the demand
 pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1 - 11</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1 - 11</u>	NO
Industrial Applicability (IA)	Claims <u>1 - 11</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-11 meet novelty.

Claims 1 - 11 lack an inventive step under PCT Article 33(3) as being obvious over Farber et al. US 2002/0162124 A1.

Farber teaches methods for identifying agents that effect cholesterol metabolism (or modulate cholesterol accumulation of), comprising exposing mutant cells to a test agent, analyzing the change in pattern of labels (or changes in cholesterol levels), and identifying the agent as one to treat or prevent aberrant cholesterol conditions (or cholesterol accumulation) (claims). Farber additionally teaches method for treating aberrant cholesterol problems (or accumulation of cholesterol) by administering the products identified. Although the reference does not teach the claimed labels or cells used in the assays, it would have been obvious to one of ordinary skill in the art to use the claimed cells as a matter of routine experimentation.

Claims 1 - 11 lack an inventive step under PCT Article 33(3) as being obvious over Shan et al. US 6465258 B1.

Shan teaches method for identifying agents that modulate cholesterol levels in mammals, and methods for treating cholesterol accumulation (abstract). Specifically, the method include cell based screening, where test compounds are contacted to labeled cells and are analyzed for cholesterol accumulation (col.12-13). Shan teaches many types of labels that can be used in the methods (col.11-12). Although the reference does not teach the claimed labels or cells used in the assays, it would have been obvious to one of ordinary skill in the art to use the claimed cells as a matter of routine experimentation.

Claims 1 - 11 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.